

PMA Decisions Rendered for November 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
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PMA Supplemental Approvals

P040021/S004 11/15/07 Panel	SJM Epic™ Valve and SJM Epic™ Supra Valve	St. Jude Medical, Inc. St. Paul , MN 55117	Approval for the Epic™ Valve in aortic sizes 21, 23, 25, 27 and 29 mm, and in mitral sizes 27, 29, 31 and 33 mm, and the SJM Epic™ Supra Valve in aortic valve sizes 19, 21, 23, 25 and 27 mm. The device is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. It may also be used as a replacement for a previously implanted aortic and/or mitral prosthetic heart valve.
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